

## **WHAT IS CLAIMED IS:**

1. A method for sterilizing a preparation containing albumin that is sensitive to ionizing radiation, said method comprising:
  - (i) reducing the residual solvent content of a preparation containing albumin to a level effective to protect said preparation containing albumin from said ionizing radiation; and
  - (ii) irradiating said preparation containing albumin with a suitable ionizing radiation at an effective rate for a time effective to sterilize said preparation containing albumin, wherein said effective rate is not constant for the duration of the sterilization procedure.
  
2. A method for sterilizing a preparation containing albumin that is sensitive to ionizing radiation, said method comprising:
  - (i) adding to a preparation containing albumin at least one stabilizer in an amount effective to protect said preparation containing albumin from said ionizing radiation; and
  - (ii) irradiating said preparation containing albumin with a suitable ionizing radiation at an effective rate for a time effective to sterilize said preparation containing albumin, wherein said effective rate is not constant for the duration of the sterilization procedure.
  
3. A method for sterilizing a preparation containing albumin that is sensitive to ionizing radiation, said method comprising:
  - (i) reducing the residual solvent content of a preparation containing albumin to a level effective to protect said preparation containing albumin from said ionizing radiation;

(ii) adding to said preparation containing albumin at least one stabilizer in an amount effective to protect said preparation containing albumin from said ionizing radiation; and

(iii) irradiating said preparation containing albumin with a suitable ionizing radiation at an effective rate for a time effective to sterilize said preparation containing albumin, wherein (i) and (ii) may be performed in any order and said effective rate is not constant for the duration of the sterilization procedure.

4. The method according to claim 1 or 3, wherein said solvent is water.

5. The method according to claim 1 or 3, wherein said solvent is an organic solvent.

6. The method according to claim 1, 2 or 3, wherein said ionizing radiation is gamma radiation.

7. The method according to claim 1, 2 or 3, wherein said effective rate comprises a rate of not more than 3.0 kGy/hour.

8. The method according to claim 1, 2 or 3, wherein said effective rate comprises a rate of more than 3.0 kGy/hour.

9. The method according to claim 1, 2 or 3, wherein said effective rate comprises a rate of not more than 6.0 kGy/hour.

10. The method according to claim 1, 2 or 3, wherein said effective rate comprises a rate of not more than 18.0 kGy/hour.

11. The method according to claim 1, 2 or 3, wherein said effective rate comprises a rate of not more than 30.0 kGy/hour.
12. The method according to claim 1, 2 or 3, wherein said preparation containing albumin is maintained in a low oxygen atmosphere.
13. The method according to claim 12, wherein said preparation containing albumin is maintained in an argon atmosphere.
14. The method according to claim 1 or 3, wherein said residual solvent content is reduced by lyophilization.
15. The method according to claim 1 or 3, wherein said residual solvent content is less than 2.0%.
16. The method according to claim 1 or 3, wherein said residual solvent content is less than 1.0%.
17. The method according to claim 1 or 3, wherein said residual solvent content is less than 0.5%.
18. The method according to claim 2 or 3, wherein said at least one stabilizer comprises at least one antioxidant.
19. The method according to claim 2 or 3, wherein said at least one stabilizer comprises at least one free radical scavenger.
20. The method according to claim 2 or 3, wherein said at least one stabilizer comprises a member selected from the group consisting of: ascorbic acid, or

a salt or ester thereof; DMSO; trehalose; mannitol, glutathione; tocopherol; polyhydric alcohols; flavanoids; and combinations of two or more thereof.

21. The method according to claim 1, 2 or 3, wherein said effective rate comprises a rate of about 3.0 kGy/hr.

22. The method according to claim 21, wherein said effective rate further comprises a rate of about 2.0 kGy/hr.

23. The method according to claim 1, 2 or 3, wherein said preparation containing albumin is irradiated at ambient temperature.

24. The method according to claim 1, 2 or 3, wherein said preparation containing albumin is irradiated at a temperature below ambient temperature.

25. The method according to claim 1, 2 or 3, wherein said preparation containing albumin is irradiated at a temperature below the eutectic point of said preparation containing albumin.

26. The method according to claim 1, 2 or 3, wherein at least one sensitizer is added to said preparation containing albumin prior to irradiating.